DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 895 and 897

[Docket No. 94N–0078]

Medical Devices; Proposed Performance Standards for Electrode Lead Wires and Proposed Banning of Unprotected Electrode Lead Wires

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish a performance standard for electrode lead wires. The agency is taking this action because it has determined that a performance standard is needed to prevent hazardous electrical connections between patients and electrical power sources. FDA is also proposing to make unprotected electrode lead wires a banned device upon the effective date of the standard for the device. FDA has determined that unprotected electrode lead wires and patient cables present an unreasonable and substantial risk of illness or injury, and that the risk cannot adequately be corrected or eliminated by labeling or a change in labeling.

DATES: Written comments by September 5, 1995. Written requests for changes in classification of the device before July 21, 1995. FDA is proposing that any final regulation promulgating a performance standard and banning the devices that do not meet the standard be effective 1 or 3 years, depending on the device type, after publication of any final rule based on this proposal.

ADDRESSES: Submit written comments and requests for changes in the classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 145.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 1994 (59 FR 26352), FDA published an advance notice of proposed rulemaking (ANPRM) and announced the need for further FDA action to address this problem. In that ANPRM, FDA described various regulatory actions it had taken since the first reported incidents in 1985 of exposed male connector pins of electrode lead wires being inserted into either alternating current (AC) power cords or a wall outlet, rather than into the patient cable that connects to the monitor. The ANPRM also described actions to various organizations, such as the former Emergency Care Research Institute (ECRI), and outside standard setting bodies have taken to prevent electrode lead wires from being connected to electrical power sources. A summary of these actions is provided later in this section. In the ANPRM, FDA stated that: ''despite efforts to eliminate the risk, unprotected electrode lead wires and patient cabling systems are still distributed by some manufacturers as replacements for existing equipment, and may also be interchangeable among various medical devices.'' (See 59 FR 26532 at 26353.) In the ANPRM, FDA further announced that it, in conjunction with the Health Industry Manufacturers Association and the American Hospital Association (AHA), was sponsoring a public conference entitled ''Unprotected Patient Cables and Electrode Lead Wires.'' The conference was held on July 15, 1994, and provided a forum for device users, manufacturers, and other health professionals to offer and to hear comments for FDA's consideration during the rulemaking process.

The need for FDA action to resolve the potential hazard of unprotected electrode lead wires and patient cables used with medical devices was further emphasized in a letter dated August 2, 1994, to FDA Commissioner David A. Kessler, from the Honorable Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology (Ref. 1). In that letter, Mr. Wyden stated that ''shocks, burns, and electrocutions occur despite warnings issued by the FDA to hospitals, manufacturers, and others.'' Specifically, Mr. Wyden wrote that:

> Hospitals have been told to purchase and use only protected wires and cables. They have also been told to remove unprotected equipment and to alert staff members to possible hazards to patients.
>
> Manufacturers have been encouraged to modify their designs to prevent lead wires from being inserted into electrical outlets.
>
> Despite warnings and other communications, some manufacturers still distribute to hospitals unprotected lead wires as replacements for deteriorated equipment.
>
> It is clear that regulatory action, as well as additional education and training is needed to stop the slow but steady flow of children (and adults) who are burned or electrocuted.

FDA's records of incidents with unprotected electrode lead wires and patient cables reveal the following: Between 1985 and 1994, 24 infants or children received ''macro-shock'' (large, externally applied currents) from electrode lead wires or cables, including 5 children who died by electrocution (Ref. 2). The most recent death (1993), which occurred in a hospital, involved a 12-day old infant. The apnea monitor involved in the incident had been sold with safety protected electrode lead wires and patient cable, but an unprotected patient cable from another manufacturer of an ECG monitor and unprotected prewired electrodes from a third manufacturer were being used when the infant was electrocuted.

There are reports of injuries associated with unsafe electrode lead wires and patient cables involving medical devices other than apnea monitors (Ref. 3). In 1986, for example, a death occurred when the ECG lead wires were plugged into an infusion pump power cord in a hospital environment. Similarly, in 1990, a death occurred when a neonatal monitor's electrode lead wires were inserted into a pulse oximeter power cord. FDA has received additional reports of similar events that resulted in electrical shocks, burns, and possible brain damage to patients. In response to the death and electrical burns that occurred in 1985, FDA issued an alert to home-use apnea monitor manufacturers, home user support organizations, and apnea monitor users, announcing, among other things, the agency's intent to embark on a cooperative effort with industry and the medical profession to resolve the problem of potential electrical connection between patients and electrical power sources. FDA also requested each home-use apnea monitor manufacturer to evaluate its device for potential electrode lead wire and patient cable hazards and, when necessary, to consider design changes to preclude insertion of electrode lead wire connectors into AC power cords and outlets. In addition to issuing the alert, the Center for Devices and Radiological Health's July 1985 ''Medical Devices Bulletin'' was devoted in great part to publicizing the unprotected electrode lead wire hazard.

Since 1985, FDA has not cleared for marketing any home-use apnea monitor that features an unprotected electrode lead wire and patient cable configuration. For all apnea monitors cleared for marketing since 1989, FDA has required a protective electrode lead

wire and cable design, whether or not the device was intended for home use. Despite these efforts, some hospitals continue to use older units, or electrode lead wires and patient cables from other devices, which do not have the protective electrode lead wire and cable design. Even with the new models, as evidenced by the 1993 incident, it may be possible to switch patient cables and/or electrode lead wires, thereby creating a hazard.

On September 3, 1993, FDA issued a safety alert to hospital administrators, risk managers, and pediatric department directors, warning them that the use of unprotected electrode lead wires with an apnea monitor may be dangerous to the patient, and may be in violation of section 518(a) of the act (21 U.S.C. 360h(a)) (Ref. 4). FDA included in the alert a number of recommendations to help prevent these accidents. FDA also sent all apnea monitor manufacturers a notification letter under section 518(a) of the act (Ref. 5).

Section 518(a) of the act authorizes the agency to issue an order to assure that adequate notification is provided in an appropriate form, by the means best suited under the circumstances involved, to all health professionals who prescribe or use a particular device and to any other person who should properly receive such notification, in order to eliminate an unreasonable and substantial harm to the public health when no other practicable means is available under the act to eliminate such risk. FDA stated that, for these devices, notification should include replacement of unprotected electrode lead wires and patient cables, and that a warning label should be permanently affixed to all monitors stating that unprotected electrode lead wires and patient cables should not be used with the device because inappropriate electrical connections may pose an unreasonable risk of adverse health consequences or death. FDA also requested manufacturers of all apnea monitors to cease further distribution of unprotected electrode lead wires and patient cables. On September 20, 1993, FDA issued a similar letter to all known third-party manufacturers of patient cables and electrode lead wires (Ref. 6).

On December 28, 1993, FDA issued a Public Health Advisory to hospital nursing directors, risk managers, and biomedical/clinical engineering departments for distribution to all units in their hospitals and outpatient clinics, as well as to home health care providers and suppliers affiliated with those facilities, advising them of the hazards associated with use of electrode lead wires with unprotected male connector pins (Ref. 7). In the Public Health Advisory, FDA expanded the scope of its September 3, 1993, apnea monitor safety alert to include all devices using patient electrodes. FDA noted that, even though manufacturers have changed the design of their devices to minimize the potential hazard, some facilities are still using older models that make it possible for staff to switch patient cables and/or lead wires, thus creating a hazard. FDA recommended various precautions to prevent the use of unsafe lead wires and patient cables.

Manufacturers of devices other than apnea monitors that utilize patient electrodes, e.g., ECG, have been encouraged by various organizations to modify their electrode lead wires so that they cannot be inserted into AC power cords or outlets. For example, in February 1987 and May 1993, ECRI issued hazard reports concerning electrical shock hazards from unprotected electrode lead wires and patient cables. Further, standards-setting bodies have developed various standards, both in draft and final form, that have the same goal in mind—safety requirements for patient electrode lead wires.

IEC has proposed an amendment to IEC 601–1, the safety standard for electromedical equipment, requiring that electrode lead wires be unable to make contact with hazardous voltages. This amendment was approved and published in March 1995.

The Underwriters Laboratories (UL) adopted IEC 601–1 by issuing its standard 2601–1. It became effective on August 31, 1994. This standard supersedes UL 544 (referenced in the ANPRM). In adopting the IEC standard, UL included a deviation that requires that patient electrodes be designed to avoid connection to electrical power sources. (See UL 2601–1, Medical Electrical Equipment Part 1: General Requirements for Safety.) The UL standard states in the rationale section that ''this is a basic safety concern prompted by recent accidents involving patient injury, including infant deaths. Patients were accidently being connected to hazardous circuits while being connected to applied parts of medical equipment, such as an apnea monitor.'' FDA has been advised that it is possible that UL will modify its requirement to be equivalent to the one included in the proposed amendment to IEC 601–1.

There is also a German DIN standard for touch proof connectors for electromedical applications. This design standard was also referenced in the ANPRM and states that it was developed because of the accidents that occurred with infants in 1985 and 1986.

The National Fire Protection Agency (NFPA) is also proposing a standard for patient electrode lead connectors. FDA has received information that even though it is voluntary, this NFPA standard will be adopted by many States and municipalities as a mandatory standard for health care facilities. Further, this standard is referenced by the Joint Commission on Health Care Organizations.

Finally, the Association for the Advancement of Medical Instrumentation (AAMI) is developing a standard that covers cables and patient lead wires for surface electrocardiographic monitoring in cardiac monitors applications. The draft standard addresses safety and performance of cables and lead wires with the added purpose of encouraging the availability of lead wires that are interchangeable for ECG monitoring applications. The standard defines a safe (no exposed metal pins) common interface at the cable yoke and lead wire connector. The draft standard is currently being balloted by AAMI and undergoing public review for acceptance as an American National Standard.

FDA believes that industry also recognizes the importance of addressing this hazard. In response to FDA's alert letter in June 1985, manufacturers voluntarily began to redesign their electrode lead wires and patient cables for home apnea monitors. And more recently, many firms have taken voluntary action to recall electrode lead wires with unprotected exposed metal pins and/or unprotected patient cables. Apnea monitor firms are replacing their male pin lead wires and associated cables with safety cable systems, usually free of charge, while others are making adapters and warning labels available. Some device manufacturers have ceased supplying unprotected electrode lead wires.

II. Highlights of the Proposal

This rule proposes to establish a performance standard that FDA believes will eliminate the risk of electrode lead wires being inserted or otherwise manipulated so as to make contact with live parts of a power outlet or separable power cord. This standard would apply to all medical devices that use patient-connected electrode lead wires.

FDA is proposing a 1- or 3-year effective date for any final regulation based on this proposed promulgation of a performance standard. Devices that would be subject to the 1-year effective date are those devices that present the

greatest potential risk of harm as demonstrated by use in environments where accidental inappropriate connections could reasonably be anticipated, and by frequent use of the devices and frequent connections of electrode lead wires. Devices subject to the 1-year effective date would also include devices that have been the subject of reported adverse events, and those that can be reasonably anticipated to be the subject of adverse events. Devices that would be subject to the 3-year effective date are those devices that do not satisfy the criteria for the 1-year effective date but also utilize unprotected electrode lead wires. The agency is also proposing to ban devices that do not meet the standard on its effective date.

III. The New Framework

As noted in the ANPRM, FDA recognizes that despite the many efforts described above, the potential risks presented by the continued use of unprotected electrode lead wires and patient cabling systems still exist. In order to eliminate these risks completely, the agency is proposing to establish a performance standard that would apply to all medical devices that use patient-connected electrode lead wires.

In reaching this decision, the agency reviewed several standards that are in various stages of development before deciding to propose to establish its own. FDA decided not to adopt these standards for this proposal because some of them were too restrictive or not restrictive enough for application to all devices. In addition, it would cause unnecessary delay in FDA's handling of this matter to obtain the appropriate clearances for the adoption of an existing standard. FDA believes, however, that devices that meet the IEC, AAMI, and NFPA standards for protected electrode lead wire and cable configurations would also meet FDA's proposed standard.

The agency believes that firms whose devices would be subject to the proposed performance standard will begin adapting existing products to the standard, or modify ''new devices'' to conform them to the standard, if they have not already done so, before the effective date of the standard. This would be consistent with Congress' admonition that ''stockpiling of nonconforming devices is discouraged, since standards will apply to all devices in commercial channels on their effective date.'' (See H. Rept. 853, 94th Cong., 2d sess. 30; see also 45 FR 7474, February 1, 1980, final standards regulations.)

FDA is publishing a list of devices utilizing patient contacting electrodes that would be subject to the 1- or 3-year phase-in process of the performance standard. FDA reserves the right, upon proper notification to interested parties, to amend this list at any time. FDA believes the proposed effective dates are reasonable and consistent with the congressional intent in enacting section 514 of the act, as well as with comments at the public conference.

To ensure a full adherence to the standard by both new and existing products in commercial distribution and use, the agency is also proposing to ban all devices that do not meet the standard on its effective date.

IV. Performance Standard

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) prescribes changes to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321–394), as amended, that improve the regulation of medical devices and strengthen the Medical Device Amendments of 1976 (the 1976 amendments), which established a comprehensive framework for the regulation of medical devices.

The SMDA amended section 513 of the act (21 U.S.C. 360c) to redefine class II as the class of devices that is or will be subject to special controls, and amended section 514 of the act (21 U.S.C. 360d) to simplify the requirements for establishing performance standards. Section 513 of the act states that the ''special controls * * * shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.'' The legislative history of the SMDA states that:

> by simplifying the process for establishing performance standards, and by allowing the Secretary discretion to employ such standards as one of a variety of additional controls to assure the safety and effectiveness of Class II devices, performance standards will become valuable tools to regulate those devices for which they are most needed.

(S. Rept. 513, 101st Cong., 2d sess. 19 (1990).)

Under this proposal, this mandatory standard would apply to all electrode lead wires, and would be phased-in over a period of 3 years. Proposed § 897.12(a) and (b) contain lists of devices that would be subject to the performance standard, with the applicable effective dates of the standard.

A. The Proposed Standard

FDA proposes the following mandatory performance standard for patient-connected electrode lead wires. Any lead wire intended to provide electrical contact between a patient and any medical device shall be protected such that the connector at the lead wire end that is distal to the patient cannot make conductive contact with an AC electrical power source (e.g., wall receptacle, power cord plug).

B. Findings

Unprotected electrode lead wires and patient cabling systems have been associated with burns and electrocutions. The fact that these injuries and deaths occurred in both homes and hospitals emphasizes the need to address this problem on a wider scale. Until all unprotected electrode lead wires and patient cables are out of the user environment, the potential hazard exists. FDA believes that a proactive approach warranted to address this potential hazard adequately.

Despite repeated efforts to eliminate the serious hazard they pose, the production and use of unprotected electrode lead wires continue. Although many firms are taking corrective action, others continue to supply users with unprotected electrode lead wires, and users continue to request and use them. Therefore, to eliminate the serious risks to health presented by these devices, FDA is proposing that all devices featuring patient connected electrode lead wires be redesigned or adapted to prevent the risk by the end of a 3-year period.

C. Opportunity to Request a Change in Classification

In accordance with section 514(b)(1)(B)(iii) of the act and § 860.132, FDA is offering interested persons an opportunity to request a change in the classification of any device that would be subject to the proposed standard, based on new information relevant to its classification. Any proceeding to reclassify a device will be in accordance with section 513(e) of the act.

A request for a change in the classification of a device that uses electrode lead wires is to be in the form of a reclassification petition containing information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 514(b)(1)(B) of the act, be submitted before July 21, 1995.

The agency advises that, to ensure timely filing of any such petition, any

request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification is submitted, FDA will, by August 21, 1995, and after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130.

In accordance with section 515(c)(1)(D) of the act (21 U.S.C. 350e(c)(1)(D)) any class III device for which a PMA is filed would be required to include information showing that the device is in compliance with the standard.

D. The Proposed Effective Date

Section 861.36 (21 CFR 861.36) states that:

> A regulation establishing * * * a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade. (See also section 514(b)(3)(B) of the act.)

FDA has determined that the cost of converting or adapting unsafe electrode lead wire configurations in order to comply with the proposed standard is manageable because the standard will be phased in over a 1- or 3-year period. Furthermore, FDA believes that this cost is justifiable given the severity of the adverse events that have occurred and those that may reasonably be anticipated.

V. Banning Action

The SMDA amended section 516 of the act (21 U.S.C. 360f), which authorizes FDA to ban any device intended for human use if FDA finds, based on all available data and information, that such device presents a ''substantial deception'' or an ''unreasonable and substantial risk of illness or injury'' that FDA finds cannot be, or has not been, corrected or eliminated by labeling or a change in labeling.

The Report by the Committee on Interstate and Foreign Commerce on the amendments (House Report) stated that:

> By using the term substantial, the Committee intends that the Secretary make a determination that the deception or risk incurred through the continued marketing of such a device is important, material, or significant. In determining that the device is deceptive, it is not necessary that the Secretary find that there was intent to mislead users of the device. Nor is actual proof of deception of or injury to an individual required.

(H. Rept. 853, 94th Cong., 2d sess. 19 (1976).)

The legislative history of the amendments further stated that:

> A finding that a device presents the requisite degree of deception or risk is made 'on the basis of all available data and information', including information which the Secretary may obtain under other provisions of the proposed legislation, and information which may be supplied by the manufacturer in response to the proceeding relating to the safety, effectiveness, or labeling of the device.

(Id. at 19.)

Under the SMDA, FDA may initiate a proceeding to ban a device, based upon available data and information, without first consulting with a device panel. In addition, the SMDA no longer requires that the agency afford interested persons an opportunity for an informal hearing before proposing a regulation to ban a device. (See Section 18(d) of the SMDA; and also 21 CFR 895.20.) FDA believes, that the conference held on July 15, 1994, was an appropriate forum for interested parties to express their views on the agency's options for a proposed course of action. Further, the ANPRM solicited comments on alternative solutions to the removal of all unprotected electrode lead wires from the market, such as banning them under part 895 (21 CFR part 895). FDA considered the conference transcript, as well as the written comments submitted in response to the ANPRM, before determining that a banning action is warranted. For all these reasons, the agency has decided that an informal hearing is not necessary before proceeding with the proposal. Moreover, this document provides interested persons with an additional opportunity to provide comments on the agency's proposed actions.

FDA is aware that in response to the section 518(a) letters it issued last year, many firms conducted voluntary recalls of unprotected electrode lead wires to correct the labeling on these devices. However, FDA has determined that the continued marketing of unprotected electrode lead wires and patient cables, no matter how they are labeled, presents an unreasonable and substantial risk of illness or injury to individuals, and provides no benefit to the public health that is not provided by protected electrode lead wires and patient cables. Use of unprotected electrode lead wires has resulted in, and can be expected to continue to result in, serious adverse consequences or death because the devices are inherently dangerous when used in a reasonably foreseeable, albeit inappropriate, manner. There are no labeling requirements that can reliably prevent inappropriate connections of unprotected electrode lead wires and, thus, unprotected electrode lead wires cannot be safely marketed for the device's intended purposes. Accordingly, FDA has not proposed a change in device labeling. Indeed, labeling warnings are meaningless when unprotected electrode wires are available to preschool children or individuals with limitations such as vision problems, mental retardation, or other cognitive impairments. Further, labeling is often an inadequate solution in certain hospital settings where health care professionals find themselves in busy, stressful situations in which they may not be provided with, or could inadvertently overlook, instructions.

Therefore, FDA is proposing to ban unprotected electrode lead wires in order to prohibit their further introduction into commerce and to expedite the removal of these devices from commercial distribution and use, thereby preventing any further or unreasonable and substantial risk of illness or injury. Based on the public comments received to date, FDA believes that the proposed 1- or 3-year effective dates would provide a reasonable transition time with minimal economic disruption.

FDA notes that, even though current law requires that hospitals and other users of medical devices report problems such as serious injuries and deaths, that law did not become effective until late 1991. Therefore, there has probably been an underreporting of the deaths and serious injuries attributable to unprotected patient electrode lead wires and cables.

VI. Summary and Analysis of Comments and FDA'S Response

The agency received 19 written comments from manufacturers, distributors, user facilities, trade associations, and a consultant in response to the ANPRM. A summary of the written comments and oral testimony from the conference is provided below:

1. In general, several comments expressed their appreciation to FDA for allowing them to express their views to the agency on this important public health issue. A few comments noted that the July conference was an excellent forum for the exchange of ideas on a subject that is of concern to all manufacturers and users of medical instrumentation. One comment encouraged FDA to increase its use of

forums of this type because they lead to a better understanding of issues that are relevant to industry. A few comments stated that they were in favor of safety systems for all devices that directly connect electrodes to patients. Other comments supported the concept of banning the use and production of unprotected electrode lead wires, provided the ban was implemented over a period of time to allow manufacturers to convert to protected electrode lead or cable sets, and for users to budget for and adapt to the change.

FDA has utilized the information gleaned from the July conference and the written comments submitted in response to the ANPRM in determining the most appropriate regulatory approach to address the risks associated with the continued use of unprotected electrode lead wires and patient cabling systems. The agency is proposing to establish a performance standard for patient-connected electrode lead wires, and also to ban devices that do not meet the standard on its effective date. However, FDA is proposing a phase-in of any final rule based on this proposal for up to a 3-year period, depending on the device type. Based on the public comments received to date, FDA believes that the proposed effective dates provide a reasonable transition period for both new and existing products in commercial distribution and use.

2. Some comments noted that interchangeability with various devices was an attractive feature of unprotected lead sets. Indeed, several comments noted that the straight male (0.80″) single pin and corresponding socket are a de facto standard. Several comments noted that this interchangeability feature helps to contain costs. Another comment noted that single lead wire electrodes are lightweight, which makes them good for use on small patients like neonates. Furthermore, because of their light weight, there is an increased probability that the lead will stay on the patient.

Interchangeability of pin-style lead wires was one of the factors leading to FDA's decision to propose this performance standard and ban. FDA believes that protected patient-connected electrode lead wires, if properly designed, can provide the same advantages that have been offered by unprotected electrode lead wires.

3. At the conference it was reported that an advantage to using unprotected electrode lead wires is the ability to clean the contacts of the lead wires, both for the electrical connection because of the oxidation of the connections and also from the standpoint of infection control. Another advantage noted was the ability to disconnect electrode lead wires from one cable and connect them into other cable assemblies while the patient is being transported from unit to unit. Other comments noted that standardized protected electrode lead wire and patient cable interfaces, if properly designed, can provide the same advantages as unprotected electrode lead wires.

FDA agrees that standardized cable and electrode lead wire interfaces, if properly designed, can provide the same advantages as unprotected electrode lead wires.

4. One comment stated that hospitals are being forced to stock many different cables and electrode lead wires to meet the needs of various types of equipment and, as a result, it makes staff training more difficult and creates complex problems when patients move from one area of the hospital to another.

FDA recognizes that in a highly complex setting, such as a hospital, there are numerous questions that arise such as when to change the electrode lead wires, when to change the cables, or when to interchange cables. FDA believes that its proposed standard will eliminate the risk of injury or death when such decisions are made because all electrode lead wires used in the hospital setting, regardless of which device they are being used with, will be protected. FDA encourages design engineers to standardize protected electrode lead wires as much as practicable to permit appropriate interchangeability among device types.

5. One comment noted that many devices (for example, devices that are no longer being manufactured) cannot be modified economically to accept a protected electrode. Another comment stated that at least 20 to 50 percent of all devices in use either cannot be converted or are not worth converting because the manufacturer is out of business or the device is obsolete. This comment states that such devices would need to be discarded and replaced with new equipment.

FDA is not aware of any devices that are no longer being manufactured and are in use today that will be unable to accept protected electrode lead wires with proper design modification. Further, to date, FDA has not been presented with any data showing that firms would be unable to economically redesign their electrode lead wires in accordance with the phase-in approach set forth in this proposal. To the contrary, the evidence in the record demonstrates that a phase-in of up to 3 years would allow sufficient time for such a conversion. For example, at the conference it was reported that clinical engineers from 33 States who responded to an independent survey stated that they could eliminate 90 percent of their nonprotected electrode lead wire and cables in about 2 years. Further, it was reported that studies conducted by AHA and the American Society for Electroneurodiagnostic Technologists (ASET) concluded that it would take a minimum of approximately 2 years to phase-in any conversion for existing electroneurodiagnostic instrumentation and electrode lead wires to a new gender configuration. This 2-year timeframe, according to a representative from ASET, was based on the financial impact that any change would have on the average diagnostic laboratory. This representative further believed that, with an extended compliance date for the diagnostic laboratory setting, the cost would be spread out over a larger fiscal period, making it easier for smaller laboratories to absorb the increased cost of services.

6. At the conference it was suggested that use of adapter blocks would be an inexpensive alternative to address the unprotected electrode lead wire problem. However, this comment noted that adapters are detachable.

FDA recognizes that certain adapters are not failure proof and can be removed, posing the same hazard as an unprotected product. FDA is seeking a permanent solution to the problem. If an adapter is used, it should be designed to prevent removal by the user.

7. One comment noted that the use of unprotected electrode lead wires is preferable to use of an intermediate adapter because adapters introduce a second electrical connection between the device and the electrode, and some devices (for example, electroencephalograms (EEG's)) are very susceptible to noise that may be generated by this additional connection.

FDA acknowledges that, if improperly designed, any extra connection that is made between the electrodes on the patient and the recorder has the potential of causing interference in the recording. However, FDA believes that significant interference could be prevented by proper design of the connector. Further, FDA believes that, in order to comply with the proposed standard, adapters would have to be designed so as to prevent their removal of the adapter by the user.

8. A few comments noted that certain devices, such as transcutaneous electrical nerve stimulators (TENS), Holter, and telemetry, may not permit conversion from unprotected to protected electrode leads unless the

device is retrofitted by an adapter and, in some cases, redesigned by the original equipment manufacturer. Several other comments noted that diagnostic instruments cannot accept redesigned electrode connections without modifying the device.

FDA believes that if devices cannot accept safety lead sets currently available, modifications can be made to the design of the lead, and may also be necessary for the device with which the lead is intended to be used. Indeed, one comment noted that modification kits will be available to permit the use of protected electrode lead wires on certain devices that currently cannot accept them.

As noted at the conference, the electrode lead wires for TENS, Holter, and other event monitors may migrate into other clinical areas. Indeed, FDA believes that the same is true for all electrode lead wires, including those intended for diagnostic use. Therefore, FDA is proposing that all unprotected electrode lead wires be redesigned or adapted to prevent the risk to health presented by these devices.

It should be noted that certain battery powered devices (e.g., Holter monitors, TENS, biofeedback devices) are proposed for Phase 1 implementation. If battery powered, these devices do not pose a direct electrical hazard. However, FDA is concerned about their unsupervised use outside a clinical setting, and the potential hazard presented when their pin-style electrode lead wires are connected to a patient instead of to a device. Based on previous adverse experiences with home-use apnea monitors, FDA believes it prudent to require early conversion of these other home-use devices, and is proposing to include them in Phase 1.

9. A trade association stated that it is not aware of any device that inherently cannot accept a redesigned, protected electrode lead. As noted in response to the comment above, FDA believes that if current devices cannot accept safety lead sets currently available, modifications can be made to the design of the lead, and may also be necessary for the device with which the lead is intended to be used. Indeed, one comment noted that modification kits will be available to permit the use of protected electrode lead wires on certain devices that currently cannot accept them.

10. Some hospitals and other providers contended that immediately replacing devices or parts would be too costly and logistically difficult. One comment stated that the cost of converting to protected electrode lead wires and patient cables would increase the costs of medical care. In contrast, one comment stated that the conversion cost to health care providers would not be unreasonably high given the potential loss of life if unprotected electrode lead wires continue to remain available. A few user facilities noted that unprotected electrode lead wires are not only less expensive than protected electrode leads, but they also have several additional advantages for hospitals, i.e., light in weight, and a standard size and shape (allowing the hospital to use the wires for multiple purposes). These facilities believe that the unprotected electrode lead wire problem will resolve itself in time because, as replacements are needed, safer leads will be ordered.

FDA believes that a long-term ''natural'' phaseout is an unacceptable solution to the problem. Indeed, one manufacturer of electrode lead wires reported that it continues to fill requests for unprotected lead wires, and does not anticipate any decrease in such requests. One comment estimated that 1.5 million unprotected electrode lead wires and patient cables are manufactured and distributed annually in the United States either for new use or as replacement products, and 10 to 40 million unprotected electrode lead wires and patient cables are currently in circulation. Moreover, FDA believes that any ''natural'' phaseout that might occur, would take much longer than is reasonable and necessary. FDA believes that a proactive approach is necessary to address this potential hazard adequately. Therefore, to eliminate the serious risks to health presented by these devices, FDA is proposing that all devices featuring patient-connected unprotected lead wires be redesigned or adapted in order to eliminate the risk by the end of a 3-year period.

11. A few comments stated that the cost of converting unsafe cables to safe cables is manageable. One comment noted that the manufacturing of electrode lead wires with protected pins, such as pins meeting DIN 42 802, costs only a few cents more than manufacturing lead wires with unprotected pins. In addition, this comment continued, the cost of the jacks that fit into the equipment is also consistent with the costs of the 2-millimeter pin jack. This comment concluded that any additional costs for new equipment are not significant compared to the cost of retrofitting equipment in the field. This comment believed that retrofitting would require significant changes to cases and printed circuit boards, and is not warranted in light of the frequency and nature of the accidents that have occurred.

FDA believes that the cost of converting or adapting unsafe electrode lead wire configurations to safe electrode lead wire configurations meeting its proposed standard is manageable because the agency will be phasing in its standard over a 1- to 3-year period. Furthermore, FDA believes that this cost is justifiable given the nature of the adverse events reported and those that may be reasonably anticipated if these devices were to remain available.

12. Several comments noted that the cost of converting to protected electrode lead wires will be greater for devices that will have to be completely redesigned to accommodate safe connections when electrode lead wires are directly inserted into them.

As noted above, FDA believes that this cost is justifiable and will be manageable given the availability of permanent adapter blocks and the range of time FDA is proposing for adherence to the standard.

13. One comment noted that the likelihood that nonmedical electrode lead wires and patient cables would be substituted for medical uses is virtually nonexistent. Another comment noted that no data are available indicating the extent of such substitution.

FDA has seen no data describing the extent of substitution of nonmedical electrode lead wires and patient cables for protected medical electrode lead wires and patient cables.

14. Some manufacturers claimed that substitution of unprotected electrode lead wires and patient cables can be avoided if the equipment is used properly and adequate warnings and instructions are provided with all devices. On the other hand, some users claimed that the reason why electrode lead wires and patient cables are misused is the poor design of the devices.

Although FDA recognizes that user education and training are essential to the proper use of all devices, including unprotected electrode lead wires, a variety of additional factors are involved when improper electrical connections are made. One of these factors is the cognitive ability of the operator, e.g., sibling, caregiver, or parent, at the time of an incident, and another factor is the environment in which the device is being used. It is worth noting that, in the Chicago hospital incident discussed earlier, the health care professional had 8 years of prior experience. Therefore, FDA believes that the most effective solution to the unprotected electrode lead wire problem is a change in the design of the device.

15. Several comments stated that there is a need for electrical safety education specific to patient cables and electrode lead wires for all personnel who come in contact with them in the patient care setting.

FDA agrees with this comment.

16. Several comments stated that there are certain areas of a hospital that present a higher risk than others for inappropriate electrical connections. These comments mentioned intensive care units (ICU's), cardiac care units (CCU's), and emergency rooms as examples of high risk areas because many times people in those areas are under stress or fatigued, and events are happening extremely quickly. Another comment noted that what was clear regarding reported deaths and macro-shocks from unprotected electrode lead wires was that there were no known reports involving adults. Therefore, this comment continued, the obvious conclusion is that neonatal ICU's, nurseries, and pediatric units where infants are cared for in a hospital should be the first priority in terms of engineering controls and education. The next areas that should be focused on are ICU's, CCU's, and possibly operating rooms. Finally, the comment concluded, areas using diagnostic devices clearly should be addressed last because of the expense of conversion and the unique attributes of that environment, including the fact that operators are trained, there are very few transactions, things are done in a linear fashion, and there is no risk of improper connections by parents, which was the cause of some of the reported incidents. A trade association added that, in any procedure-based area in a hospital, e.g., the catheter lab, the probability of a problem occurring with a single bare-pin lead electrode and a female end of a power cord is diminished.

FDA has considered the environments where these devices are used, the frequency with which they are used and the reported and reasonably anticipated potential adverse events in determining whether specific devices should be subject to either the 1- or the 3-year effective date of the standard.

FDA believes that, even though current law requires that hospitals and other users of medical devices report serious injuries and deaths, there probably has been underreporting of deaths and serious injuries caused by unprotected patient electrode lead wires. FDA believes that most of the deaths, particularly those involving infants, probably have been reported to FDA. However, the agency believes that some injuries, that could be related to these devices, including serious injuries, probably have not been reported.

17. Many comments stated that the risk analysis and the history of incidents involving ECG and apnea monitoring equipment support a need for a performance standard for these devices. One comment at the conference noted that intraoperative EEG monitoring equipment should be included in any FDA regulatory action because the leads used with this equipment are similar to those used with the ECG and apnea monitoring.

FDA believes that all unprotected electrode lead wires present a risk for patients connected to them and, therefore, would be subject to the proposed performance standard and ban.

18. One comment suggested that new devices should be required to have a permanently wired cord. In contrast, another comment noted that hardwiring the modular power cord to the equipment is a poor alternative in light of the costs and logistical feasibility of this action. The modular power cord, this comment continued, is inherently safe and is a standard across the entire industry base. This comment believes that the problem is not the power cords, but rather the lead wires and the lack of training of the individuals using them.

FDA believes that hardwiring the power cord to the monitor is not a solution to the hazard presented by an exposed male pin. FDA's proposed actions, therefore, focus on the unprotected electrode lead wire, where an inappropriate connection can be made.

19. One comment recommended changing the ECG monitoring color codes for lead placement to avoid duplication with those used for the power cord.

FDA believes that a color change is not the most appropriate and direct solution to the problem. As noted above, several factors play a role in an improper connection.

20. During the conference it was stated that the detached power cord was the primary source for all of the incidents involving macro-shocks and deaths associated with unprotected lead wires. Furthermore, it was noted that there have been no accidents in the home, resulting in either injuries or deaths, since 1987. All of the accidents that have occurred since then have occurred in a hospital setting.

As noted in comment 18, FDA believes that the characteristics of the power cord can not eliminate the hazard presented by an exposed male pin. Therefore, FDA's proposed actions focus on the unprotected electrode lead wires. Since 1985, unprotected electrode lead wires have been associated with burns and electrocutions in both homes and hospitals. Therefore, FDA does not believe that the focus of its proposed actions should be limited to a specific environment. FDA has considered the intended environments of use, however, in determining when the proposed requirements would be applicable to a particular device.

21. Several comments objected to the notion that one standard could be appropriate for electrode lead wires and patient cables used in multiple diagnostic procedures because the performance attributes are different.

FDA believes that the proposed standard provides enough flexibility for manufacturers to design safety leads that take into account the type of diagnostic procedure involved, the physical characteristics of each examination and operating room, as well as each physician's or technician's personal preference for use of the diagnostic instrument on the patient. Hence, FDA has determined that one performance standard would be appropriate for all electrode types.

22. Several comments recommended that a risk-based assessment of the unprotected electrode lead problem should be a component of any FDA action. Devices that present the greatest risk should be given the greatest attention.

FDA has determined that all devices that use electrode lead wires should be subject to the proposed performance standard and ban. However, FDA has decided to phase-in its proposed requirements to allow sufficient flexibility for all devices that use unprotected electrode lead wires to be converted. As noted in the response to comment 20, FDA considered risk in determining when the proposed requirements would be applicable to a particular device.

23. One comment stated that lead wire connectors should not have exposed metal that can be connected to a ground or power source, either foreign or domestic.

FDA agrees. Therefore, its proposed standard attempts to achieve this goal.

24. Several comments stated that a performance standard should be focused on line-powered devices and, even more specifically, on apnea monitoring and ECG devices, for which there have been reported adverse incidents. One comment added that other devices should not be required to change to protected electrode lead wires until they are shown to present a risk to patients.

FDA is proposing to apply its standard to all devices featuring

electrode lead wires. As noted earlier, limiting the standard to certain devices would not eliminate the risk of interchanging unprotected electrode lead wires with protected electrode lead wires. Further, FDA considered the reported and reasonably anticipated potential adverse events in determining whether a device should be subject to the 1- or 3-year effective date.

25. One comment noted that FDA should adopt a safety standard such as UL 544 in lieu of a performance or design standard, such as AAMI's. Several other comments asserted that FDA should establish a performance standard. Another comment suggested that, if a general patient safety standard is desired, the language of the UL standard would suffice. This standard, the comment continued, permits the use of unprotected electrode lead wires and cables so long as the overall design of the system prevents exposing the patient to main power. If a performance standard specific to electrode lead wires and cables is desired, then it would be appropriate to establish a standard that requires that all electrical connections that can be manually opened be designed so that insertion into AC power sockets is not possible.

FDA believes that its proposed performance standard sufficiently addresses the hazard to be prevented, while providing design engineers flexibility in determining how to accomplish that goal.

26. Some comments noted that a performance standard across device type is viable assuming that manufacturers are given a reasonable time to convert to this performance standard. One comment argued that existing devices should be permitted to be ''grandparented'' in.

FDA is requiring that both new and existing devices be subject to the standard. FDA believes that its phase-in approach will provide sufficient time for conversion and is consistent with the statutory requirements with respect to applicability of a performance standard. Therefore, there will be no ''grandparenting'' of existing equipment.

27. One comment expressed the view that standards committees which are currently in place are best prepared to address the unique requirements of various devices, and that existing standards organizations, such as AAMI, should be encouraged to increase emphasis in this area. Indeed, in the conference it was noted, for example, that the IEC has developed at least four standards for connectors for specific devices.

FDA encourages standards organizations to continue their efforts in this area. However, as stated earlier in this proposal, these are voluntary standards, and the agency has determined that a mandatory standard is necessary to adequately address the risk to health presented by unprotected electrode lead wires. The agency has used these standards in developing its proposed mandatory performance standard. FDA believes that the proposed standard achieves the goal of the existing standards—to eliminate the risk of patient-connected electrode lead wires being inserted or otherwise manipulated so as to make contact with live parts of a power outlet or separable power cord.

28. During the conference a concern was raised that, if FDA were to require a protected environment, equipment currently in place could no longer be used. This comment stated that some equipment lasts more than 10 years. Therefore, it was the comment's recommendation that protected electrode lead wires and cables be required to work with devices in place today.

FDA agrees with this comment. FDA encourages design engineers to consider the ''useful life'' of the existing devices subject to this proposal when determining how to convert from an unprotected electrode lead wire and patient cable configuration to a protected configuration.

29. Several comments recognized that requiring that only new equipment be changed would not adequately solve the problem.

FDA believes that, until all unprotected electrode lead wires are off the market, the potential hazard still exists. Therefore, to ensure full adherence to the performance standard by all unprotected electrode lead wires currently in commercial distribution or those already sold to the ultimate user, FDA is proposing to ban all devices not meeting the performance standard on its effective date.

30. A couple of comments supported the concept of banning the use and production of unprotected electrode lead wires. These comments recommended that such a ban be implemented over a period of time to allow manufacturers to convert to protected electrode lead or cable sets, and to allow users to budget for and adapt to the change. Comments varied with respect to the timeframe in which they believed the ban should be applied. One comment believed that full conversion should be required after approximately 18 months. Another comment noted that an immediate ban would result in interruption in hospital service and increased costs. Another comment noted that a total phaseout could be accomplished in 2 years.

FDA is proposing to phase-in the ban in the same manner as the performance standard. Thus, the ban would apply on the effective date of the standard.

31. One comment opposed to banning stated that such an action would shut down many areas of a hospital until the equipment could be converted.

As noted earlier, the proposed ban would be phased in over a 1- and 3-year period. This gradual phase-in would allow hospitals to take appropriate measures to convert or adapt existing equipment and thereby minimize, if not eliminate, the potential shortage of certain devices in the hospital.

32. One comment stated that a performance standard would probably not prevent substitution or removal of offending cables and leads that are being used with products that have already been shipped.

FDA believes that its proposed dual regulatory approach of a performance standard and ban for new and existing products would prevent further use of devices already shipped. As stated previously, both the standard and the ban would apply to all devices subject to these actions on the effective date. Any device not in compliance with these requirements would be adulterated in accordance with section 501(e) of the act (21 U.S.C. 351(e)) and/or section 501(g) (21 U.S.C. 351(g)).

33. One comment stated that FDA should identify cable manufacturers not registered with the agency, or who have not filed 510(k)'s and take compliance action against them.

FDA agrees with this comment, and has examined the regulatory status of many cable and lead wire manufacturers and contract manufacturers during the past year. FDA will continue to monitor firms that have not registered and/or listed, or submitted 510(k)'s, with the agency. FDA invites further information regarding any manufacturer believed to be in violation of these requirements.

34. A few comments noted that FDA should require that any device for which a new 510(k) is filed meet safety requirements (UL, IEC, AAMI).

As discussed previously, FDA considered adoption of a voluntary standard e.g., UL, IEC, AAMI, to address the unprotected electrode lead wire hazard, but decided instead to initiate the regulatory process for developing a mandatory performance standard for patient-connected electrode lead wires. If a final rule is promulgated establishing this standard and banning devices that do not meet the standard on its effective date, it will be applicable to

both new devices and existing products in commercial distribution and use.

35. A request was made that FDA control third-party suppliers (manufacturers of cables and lead wires) by requiring 510(k)'s from them.

A third party supplier that manufactures cable and lead wires is subject to the requirements of section 510(k) if that supplier also distributes the cables and lead wires. (See 21 CFR 807.85 for a discussion of exemptions from premarket notification requirements.)

36. Some comments questioned how device modifications from an unprotected electrode lead wire and patient cable configuration to a protected configuration will be handled by the Center for Devices and Radiological Health's Office of Device Evaluation (ODE). These comments noted that, if protected electrode leads were required on equipment, the change would have to be processed through the premarket notification process (510(k) process), which could result in a delay.

In a document entitled ''Notification of Implementation of Lead Wires and Patient Cable Changes to Safe Configurations,'' dated February 15, 1995, ODE stated that, for devices reviewed through the 510(k) process, information regarding device modification to the protected configuration should be submitted as an addendum to the existing premarket notification file. FDA noted that, in the interest of public health, it is not requiring a new 510(k) and/or prior clearance if the only change being made is to a protected configuration. For devices reviewed through the premarket approval process, a modification from an unprotected electrode lead wire and patient cable configuration to a protected configuration may also be implemented without prior clearance by FDA. FDA stated that, for these devices, information regarding device modifications to the protected configuration should be provided in the next annual report to the premarket approval application. In both instances, FDA stated that, within 90 days of the receipt of the information, it will notify parties of any concerns it may have with the proposed safe configuration design. Otherwise, no response will be provided. Please refer to this ODE document, which is available from the Division of Small Manufacturers Assistance (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or 1–800–638–2041, prior to making your submission.

37. A trade association recommended the use of a guidance document in lieu of a new regulation or mandatory standard concerning protected cable and lead sets.

FDA has been recommending, advising, and warning about the hazard presented by unprotected electrode lead wires for 10 years. FDA has decided that firmer regulatory action is warranted.

VII. Enforcement

FDA's statutory authority to issue performance standards is derived from section 514 of the act. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to promulgate binding regulations for the efficient enforcement of the act. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals Inc.*, 412 U.S. 645, 653 (1973); *National Assn. of Pharmaceuticals Manufacturers* v. *FDA*, 637 F.2d 877 (2d Cir. 1981); *National Confectioners Assn.* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978); *National Nutritional Foods Assn.* v. *Weinberger*, 512 F.2d 688 (2d Cir.), cert. denied, 423 U.S. 827 (1975). Section 519(a) of the act (21 U.S.C. 360i(a)) also authorizes the agency to issue regulations requiring manufacturers of devices to maintain and provide records to ensure that devices are not adulterated, misbranded, unsafe, or ineffective. FDA's performance standards for medical devices are substantive regulations with the force and effect of law. See *United States* v. *Undetermined Quantities of Various Articles of Device* * * * *Proplast II*, 800 F. Supp. 499, 502 (S.D. Tex. 1992); *United States* v. *789 Cases* * * * *Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1287 (D.P.R. 1992).

Section 501(e) of the act deems a device to be adulterated, and thus prohibited from commerce, if it is a device subject to a performance standard established under section 514 of the act, unless such device is in all respects in conformity with such standard. Introduction into interstate commerce of a device that fails to comply with the requirements established by section 514 of the act is a prohibited act under section 301(a) of the act (21 U.S.C. 331(a)), and the agency will use its enforcement powers to deter noncompliance. Persons who violate section 301 of the act may be subject to injunction pursuant to section 302(a) of the act (21 U.S.C. 332(a)). In addition, any person responsible for violating section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)) and criminal prosecution under section 303(a) of the act.

Section 501(g) of the act deems a device to be adulterated, and thus prohibited from commerce, if it is a banned device. Section 304(a)(2) of the act (21 U.S.C. 334(a)(2)) authorizes seizure of any adulterated device at any time. In any action involving devices, section 709 of the act (21 U.S.C. 379a) establishes a statutory presumption of interstate commerce for any device in commerce. Consequently, once FDA makes a device a banned device, in subsequent regulatory proceedings to remove the device from commerce, the Government need show only that the device has been banned; the Government is not required to cite evidence in court to establish any of the elements usually necessary to prove that the device is adulterated and should be condemned.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The provisions of the proposed rule, including the establishment of a performance standard and ban of the applicable devices not meeting the standard, are consistent with the industry's response to the hazard presented by medical devices that use unprotected electrode lead wires. Indeed, efforts have already begun to convert to unprotected electrode lead wire and patient cable configurations either by redesigning new equipment or permanently affixing adapters to

existing products. The industry has commented that this conversion to protected electrode lead wires and patient cables could occur over a maximum of 2 years. FDA's proposal, if implemented, would be phased in over a 3-year period. This proposed phase-in would further minimize the costs associated with such a conversion. For these reasons, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

X. Request for Comments

Interested persons may, on or before September 21, 1995, submit to the Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA is soliciting comments on all aspects of this proposal, and specifically requests comments on the following issues:

(1) Cost of converting or adapting unsafe electrode lead wire configurations to safe electrode lead wire configurations that meet the proposed requirements in this document. Please provide the source of your estimates.

(2) The list of devices subject to the proposed performance standard and ban, and their respective effective dates for compliance.

(3) The potential for cutaneous electrodes to be interchanged with various medical equipment.

(4) Test methods, if any, that should be included in the proposed mandatory standard.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter to FDA Commissioner David A. Kessler from Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, dated August 2, 1994.

2. Information from FDA's medical device reporting (MDR) data base, Rockville, MD.

3. Information from FDA's medical device reporting (MDR) data base, Rockville, MD.

4. ''FDA Safety Alert: Unsafe Patient Lead Wires and Cables,'' FDA's September 3, 1993, Safety Alert.

5. Section 518(a) notification letter to apnea monitor manufacturers, September 3, 1993.

6. Section 518(a) notification letter to patient cable and lead wire manufacturers, September 20, 1993.

7. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices, December 28, 1993.

List of Subjects

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

21 CFR Part 897

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Title 21, Chapter I of the Code of Federal Regulations be amended as follows:

PART 895—BANNED DEVICES

1. The authority citation for 21 CFR part 895 continues to read as follows:

Authority: Secs. 502, 516, 518, 519, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360f, 360h, 360i, 371).

2. Section 895.105 is added to subpart B to read as follows:

§ 895.105 Unprotected electrode lead wire.

(a) *Definition.* A lead wire that is intended to provide electrical contact between a patient and any medical device and that has a connector that is not protected at the end distal to the patient, i.e., the connector at the lead wire end that is distal to the patient is capable of making conductive contact with an alternating current electrical power source (e.g., wall receptacle, power cord plug).

(b) *Applicability.* Devices utilizing unprotected patient connected electrode lead wires shall be banned as of the date set forth in paragraph (c) of this section.

(c) *Effective date.* The effective date for the ban of devices utilizing unprotected patient-connected electrode lead wires as defined in paragraph (a) of this section shall be as follows:

(1) For the following devices, the effective date for which compliance is required is (insert date 1 year after date of publication of the final rule):

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

[Insert date 1 year after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radiofrequency.
1	74 DRK	870.5300	III	DC-Defibrillator, High Energy, (Including Paddles).
1	74 DRO	870.5550	III	Pacemaker, Cardiac, External Transcutaneous (Noninvasive).
1	74 DRQ	870.2060	II	Amplifier and Signal Conditioner, Transducer Signal.
1	74 DRR	870.2050	II	Amplifier and Signal Conditioner, Biopotential.
1	74 DRT	870.2300	II	Monitor, Cardiac (Including Cardiotachometer and Rate Alarm).
1	74 DRW	870.2350	II	Adaptor, Lead Switching, Electrocardiograph.
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient, (Including Connector).
1	74 DSB	870.2770	II	Plethysmography, Impedance.
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DSJ	870.1100	II	Alarm, Blood Pressure.
1	74 DSK	870.1110	II	Computer, Blood Pressure.

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE—Continued

[Insert date 1 year after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
1	74 DSR	870.3850	III	Stimulator, Carotid Sinus Nerve.
1	74 DTE	870.3600	III	Pulse Generator, Pacemaker, External.
1	74 DXG	870.1435	II	Computer, Diagnostic, Preprogrammed, Single-Function.
1	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.
1	74 DXJ	870.2450	II	Display, Cathode-Ray Tube, Medical.
1	74 DXK	870.2330	II	Echocardiograph.
1	74 DXN	870.1130	II	System, Measurement, Blood Pressure, Noninvasive.
1	74 DYC	870.2400	II	Vectorcardiograph.
1	74 JOQ	870.1750	II	Generator, Pulse, Pacemaker, External Programmable.
1	74 KRC	870.2370	II	Tester, Electrode, Surface, Electrocardiographic.
1	74 KRE	870.3640	II	Analyzer, Pacemaker Generator Function, Indirect.
1	74 KRG	870.3700	III	Programmer, Pacemaker.
1	74 LDD	870.5300	II	DC-Defibrillator, Low-Energy, (Including Paddles).
1	74 LDF	870.3680	II/III	Electrode, Pacemaker, Temporary.
1	74 LIW	.....	II	Fibrillator, AC.
1	74 LOR	.....		Resuscitator, Trans-Telephonic.
1	74 LOS	870.2340	II	System, ECG Analysis.
1	74 LPA	.....	III	System, Esophageal Pacing.
1	74 LPD	.....	III	System, Pacing, Antitachycardia.
1	78 LIL	.....		Monitor, Penile Tumescence.
1	78 KPN	876.2040	II	Alarm, Enuresis.
1	78 KPI	876.5320	II	Stimulator, Electrical, Nonimplanted, for Incontinence.
1	84 GWF	882.1870	II	Stimulator, Electrical, Evoked Response.
1	84 GWK	882.1845	II	Conditioner, Signal, Physiological.
1	84 GWL	882.1835	II	Amplifier, Physiological Signal.
1	84 GWN	882.1460	II	Nystagmograph.
1	84 GXY	882.1320	II	Electrode, Cutaneous.
1	84 GXZ	882.1350	II	Electrode, Needle.
1	84 GYE	882.1855	II	System, Telemetry, Physiological Signal.
1	84 GZI	882.5810	II	Stimulator, Neuromuscular, External Functional.
1	84 GZJ	882.5890	II	Stimulator, Nerve, Transcutaneous, for Pain Relief.
1	84 GZO	882.1540	II	Device, Galvanic Skin Response Measurement.
1	84 HCC	882.5050	II	Device, Biofeedback.
1	84 HCJ	882.1560	II	Device, Skin Potential Measurement.
1	84 JXE	882.1550	II	Device, Nerve Conduction Velocity Measurement.
1	84 JXK	882.5800	III	Stimulator, Cranial Electrotherapy for Speech Disorder.
1	84 LIH	.....		Interferential Current Therapy.
1	86 HLZ	886.1220	II	Electrode, Corneal.
1	86 HMC	886.1510	II	Monitor, Eye Movement.
1	86 HLL	886.1510	II	Monitor, Eye Movement.
1	89 IKD	890.1175	I	Cable, Electrode (for Use With Diagnostic Physical Medicine Devices).

(2) For the following devices, the effective date for which compliance is required is (insert date 3 years after date of publication of the final rule):

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

[Insert date 3 years after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
2	73 KOI	868.2775	II	Stimulator, Nerve, Peripheral, Electrical.
2	74 DQH	870.2310	II	Cardiograph, Apex (Vibrocardiograph).
2	74 DQK	870.1425	II	Computer, Diagnostic, Programmable.
2	74 DQX	870.1330	II	Wire, Guide, Computer.
2	74 DTA	870.3720	II	Tester, Pacemaker Electrode Function.
2	74 DTC	870.3630	II	Analyzer, Pacemaker Generator Function.
2	74 DTD	870.3620	III	Adaptor, Lead, Pacemaker.
2	74 KRI	870.4200	I	Accessory Equipment, Cardiopulmonary Bypass.
2	74 LIX	.....		Aid, Cardiopulmonary Resuscitation.
2	76 LYD	.....	III	Stimulator, Electromagnetic Bone Growth for Dental Use.
2	78 MII	.....		System, Gallbladder Thermal Ablation.
2	78 LNL	.....		Stimulator, Electrical, for Sperm Collection.
2	78 LST	.....		Device, Erectile Dysfunction (only Cavonsometry).
2	78 KDO	876.1500	II	Rongeur, Hot Cystoscopic.
2	78 EXQ	876.1620	II	Cystometer, Electrical Recording.
2	78 FAP	876.1620	II	Cystometric (CO_2) on Hydraulic Device.
2	78 FEN	876.1620	II	Device, Hydraulic Cystometric.
2	78 EXS	876.1800	II	Urinometer, Electrical (only with electromyography (EMG) electrodes).

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE—Continued

[Insert date 3 years after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
2	78 EXY	876.1800	II	Uroflowmeter (only with EMG electrodes).
2	78 FHC	876.4300	II	Adaptor to the Cord, for Transurethral Surgical Instrument.
2	78 FGW	876.4300	II	Clamp, Electrical.
2	78 FBJ	876.4300	II	Cord, Electric for Transurethral Surgical Instrument.
2	78 FHZ	876.4300	II	Desiccator, Transurethral.
2	78 FAS	876.4300	II	Electrode, Electrosurgical, Active, Urological.
2	78 FEH	876.4300	II	Electrode, Flexible Suction Coagulator.
2	78 KGE	876.4300	II	Forceps, Biopsy, Electric.
2	78 FDB	876.4300	II	Plate, Patient.
2	78 FDI	876.4300	II	Snare, Flexible.
2	78 FDJ	876.4300	II	Snare, Rigid Self-Opening.
2	78 FFI	876.4300	II	System, Alarm, Electrosurgical.
2	78 FAR	876.4300	II	Unit, Electrosurgical.
2	78 KNS	876.4300	II	Unit, Electrosurgical (and Accessories).
2	78 FDL	876.4300	II	Wristlet, Patient Return.
2	78 EZL	876.5130	II	Catheter, Balloon Retention Type.
2	79 GEI	878.4400	II	Device, Electrosurgical, Cutting and Coagulation and Accessories.
2	79 JOS	878.4400	II	Electrode, Electrosurgical.
2	84 GWQ	882.1400	II	Electroencephalograph.
2	84 GXC	882.5940	III	Device, Electroconvulsive Therapy.
2	84 GXS	882.1610	II	Monitor, Alpha.
2	84 GYC	882.1310	II	Electrode, Cortical.
2	84 GZK	882.1340	II	Electrode, Nasopharyngeal.
2	84 GZL	882.1330	II	Electrode, Depth.
2	84 GZN	882.1825	III	Rheoencephalograph.
2	84 HCB	882.5235	II	Device, Adverse Conditioning.
2	85 HII	884.5940	III	Stimulator, Vaginal, Muscle, Powered, for Therapeutic Use.
2	86 HLT	886.1640	II	Preamplifier, Ophthalmic.
2	86 HQR	886.4100	II	Apparatus, Electrocautery, Radio Frequency.
2	86 HQO	886.4115	II	Unit, Cautery, Thermal.
2	86 HRO	886.4250	II	Unit, Electrolysis, Ophthalmic.
2	86 HQC	886.4670	II	System, Phacofragmentation.
2	86 HQE	886.4150	II	Instrument, Vitreous Aspiration & Cutting.
2	87 KQX	888.1500	I	Goniometer, AC-Powered.
2	87 LBB	888.1240	II	Dynamometer, AC-Powered.
2	87 LOF	.....	III	Stimulator, Bone Growth, Noninvasive.
2	87 LWB	.....	III	Stimulator, Functional Neuromuscular, Scoliosis.
2	89 EGJ	890.5525	III	Device, Iontophoresis, Other Uses.
2	89 KTB	890.5525	II	Device, Iontophoresis, Specific Uses.
2	89 IKN	890.1375	II	Electromyograph, Diagnostic.
2	89 IKP	890.1225	II	Chronaximeter.
2	89 IKT	890.1385	II	Electrode, Needle, Diagnostic Electromyograph.
2	89 IMG	890.5860	II/III	Stimulator, Ultrasound and Muscle, for Use in Applying Therapeutic Deep Heat.
2	89 IPF	890.5850	II	Stimulator, Muscle, Powered.
2	89 ISB	890.1850	II	Stimulator, Muscle, Diagnostic.
2	89 LPQ	890.5860	II/III	Stimulator, Ultrasound and Muscle.
2	89 MBN	.....	III	Stimulator, Muscle, Powered, Invasive.
2	89 MKD	.....	III	Stimulator, Functional Walking Neuromuscular, Noninvasive.
2	90 LNH	892.1000	II	System, Imaging, Nuclear Magnetic Resonance.

3. New part 897 is added to read as follows:

PART 897—PERFORMANCE STANDARD FOR PATIENT-CONNECTED ELECTRODE LEAD WIRES

Sec.

Authority: Secs. 501, 502, 513, 514, 530–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374); secs. 351, 361 of the Public Health Service Act (42 U.S.C. 262, 264).

§ 897.10 Applicability.

Devices utilizing electrode lead wires intended to be connected to patients shall be subject to the standard set forth in section 897.11.

§ 897.11 Performance standard.

Any lead wire intended to provide electrical contact between a patient and any medical device shall be protected such that the connector at the lead wire end that is distal to the patient cannot make conductive contact with an alternating current electrical power source (e.g., wall receptacle, power cord plug).

§ 897.12 Effective date.

The effective date for compliance with the standard set forth in 897.11(a) shall be as follows:

(a) For the following devices the effective date for which compliance is required is (insert date 1 year after date of publication of the final rule):

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

[Insert date 1 year after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radiofrequency.
1	74 DRK	870.5300	III	DC-Defibrillator, High Energy (Including Paddles).
1	74 DRO	870.5550	III	Pacemaker, Cardiac, External Transcutaneous (Noninvasive).
1	74 DRQ	870.2060	II	Amplifier and Signal Conditioner, Transducer Signal.
1	74 DRR	870.2050	II	Amplifier and Signal Conditioner, Biopotential.
1	74 DRT	870.2300	II	Monitor, Cardiac (Including Cardiotachometer and Rate Alarm).
1	74 DRW	870.2350	II	Adaptor, Lead Switching, Electrocardiograph.
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient (Including Connector).
1	74 DSB	870.2770	II	Plethysmograph, Impedance.
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DSJ	870.1100	II	Alarm, Blood Pressure.
1	74 DSK	870.1110	II	Computer, Blood Pressure.
1	74 DSR	870.3850	III	Stimulator, Carotid Sinus Nerve.
1	74 DTE	870.3600	III	Pulse Generator, Pacemaker, External.
1	74 DXG	870.1435	II	Computer, Diagnostic, Preprogrammed, Single-Function.
1	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.
1	74 DXJ	870.2450	II	Display, Cathode-Ray Tube, Medical.
1	74 DXK	870.2330	II	Echocardiograph.
1	74 DXN	870.1130	II	System, Measurement, Blood Pressure, Non-invasive.
1	74 DYC	870.2400	II	Vectorcardiograph.
1	74 JOQ	870.1750	II	Generator, Pulse, Pacemaker, External Programmable.
1	74 KRC	870.2370	II	Tester, Electrode, Surface, Electrocardiographic.
1	74 KRE	870.3640	II	Analyzer, Pacemaker Generator Function, Indirect.
1	74 KRG	870.3700	III	Programmer, Pacemaker.
1	74 LDD	870.5300	II	DC-Defibrillator, Low-Energy (Including Paddles).
1	74 LDF	870.3680	II/III	Electrode, Pacemaker, Temporary.
1	74 LIW	.....	II	Fibrillator, AC.
1	74 LOR	.....		Resuscitator, Trans-Telephonic.
1	74 LOS	870.2340	II	System, ECG Analysis.
1	74 LPA	.....	III	System, Esophageal Pacing.
1	74 LPD	.....	III	System, Pacing, Antitachycardia.
1	78 LIL	.....		Monitor, Penile Tumescence.
1	78 KPN	876.2040	II	Alarm, Enuresis.
1	78 KPI	876.5320	II	Stimulator, Electrical, Nonimplanted, for Incontinence.
1	84 GWF	882.1870	II	Stimulator, Electrical, Evoked Response.
1	84 GWK	882.1845	II	Conditioner, Signal, Physiological.
1	84 GWL	882.1835	II	Amplifier, Physiological Signal.
1	84 GWN	882.1460	II	Nystagmograph.
1	84 GXY	882.1320	II	Electrode, Cutaneous.
1	84 GXZ	882.1350	II	Electrode, Needle.
1	84 GYE	882.1855	II	System, Telemetry, Physiological Signal.
1	84 GZI	882.5810	II	Stimulator, Neuromuscular, External Functional.
1	84 GZJ	882.5890	II	Stimulator, Nerve, Transcutaneous, for Pain Relief.
1	84 GZO	882.1540	II	Device, Galvanic Skin Response Measurement.
1	84 HCC	882.5050	II	Device, Biofeedback.
1	84 HCJ	882.1560	II	Device, Skin Potential Measurement.
1	84 JXE	882.1550	II	Device, Nerve Conduction Velocity Measurement.
1	84 JXK	882.5800	III	Stimulator, Cranial Electrotherapy for Speech Disorder.
1	84 LIH	.....		Interferential Current Therapy.

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE—Continued

[Insert date 1 year after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
1	86 HLZ	886.1220	II	Electrode, Corneal.
1	86 HMC	886.1510	II	Monitor, Eye Movement.
1	86 HLL	886.1510	II	Monitor, Eye Movement.

(b) For the following devices the effective date for which compliance is required is (insert date 3 years after date of publication of the final rule):

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

[Insert date 3 years after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
2	73 KOI	868.2775	II	Stimulator, Nerve, Peripheral, Electrical.
2	74 DQH	870.2310	II	Cardiograph, Apex (Vibrocardiograph).
2	74 DQK	870.1425	II	Computer, Diagnostic, Programmable.
2	74 DQX	870.1330	II	Wire, Guide, Computer.
2	74 DTA	870.3720	II	Tester, Pacemaker Electrode Function.
2	74 DTC	870.3630	II	Analyzer, Pacemaker Generator Function.
2	74 DTD	870.3620	III	Adaptor, Lead, Pacemaker.
2	74 KRI	870.4200	I	Accessory Equipment, Cardiopulmonary Bypass.
2	74 LIX	.....		Aid, Cardiopulmonary Resuscitation.
2	76 LYD	.....	III	Stimulator, Electromagnetic Bone Growth for Dental Use.
2	78 MII	.....		System, Gallbladder Thermal Ablation.
2	78 LNL	.....		Stimulator, Electrical, for Sperm Collection.
2	78 LST	.....		Device, Erectile Dysfunction (only Cavonsometry).
2	78 KDO	876.1500	II	Rongeur, Hot Cystoscopic.
2	78 EXQ	876.1620	II	Cystometer, Electrical Recording.
2	78 FAP	876.1620	II	Cystometric (CO2) on Hydraulic Device.
2	78 FEN	876.1620	II	Device, Hydraulic Cystometric.
2	78 EXS	876.1800	II	Urinometer, Electrical (only with EMG electrodes).
2	78 EXY	876.1800	II	Uroflowmeter (only with EMG electrodes).
2	78 FHC	876.4300	II	Adaptor to the Cord, for Transurethral Surgical Instrument.
2	78 FGW	876.4300	II	Clamp, Electrical.
2	78 FBJ	876.4300	II	Cord, Electric for Transurethral Surgical Instrument.
2	78 FHZ	876.4300	II	Desiccator, Transurethral.
2	78 FAS	876.4300	II	Electrode, Electrosurgical, Active, Urological.
2	78 FEH	876.4300	II	Electrode, Flexible Suction Coagulator.
2	78 KGE	876.4300	II	Forceps, Biopsy, Electric.
2	78 FDB	876.4300	II	Plate, Patient.
2	78 FDI	876.4300	II	Snare, Flexible.
2	78 FDJ	876.4300	II	Snare, Rigid Self-Opening.
2	78 FFI	876.4300	II	System, Alarm, Electrosurgical.
2	78 FAR	876.4300	II	Unit, Electrosurgical.
2	78 KNS	876.4300	II	Unit, Electrosurgical (and Accessories).
2	78 FDL	876.4300	II	Wristlet, Patient Return.
2	78 EZL	876.5130	II	Catheter, Balloon Retention Type.
2	79 GEI	878.4400	II	Device, Electrosurgical, Cutting and Coagulation and Accessories.
2	79 JOS	878.4400	II	Electrode, Electrosurgical.
2	84 GWQ	882.1400	II	Electroencephalograph.
2	84 GXC	882.5940	III	Device, Electroconvulsive Therapy.
2	84 GXS	882.1610	II	Monitor, Alpha.
2	84 GYC	882.1310	II	Electrode, Cortical.
2	84 GZK	882.1340	II	Electrode, Nasopharyngeal.
2	84 GZL	882.1330	II	Electrode, Depth.

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE—Continued

[Insert date 3 years after date of publication of the final rule]

Phase	Product code	CFR section	Class	Device name
2	84 GZN	882.1825	III	Rheoencephalograph.
2	84 HCB	882.5235	II	Device, Adverse Conditioning.
2	85 HII	884.5940	III	Stimulator, Vaginal, Muscle, Powered, for Therapeutic Use.
2	86 HLT	886.1640	II	Preamplifier, Ophthalmic.
2	86 HQR	886.4100	II	Apparatus, Electrocautery, Radio Frequency.
2	86 HQO	886.4115	II	Unit, Cautery, Thermal.
2	86 HRO	886.4250	II	Unit, Electrolysis, Ophthalmic.
2	86 HQC	886.4670	II	System, Phacofragmentation.
2	86 HQE	886.4150	II	Instrument, Vitreous Aspiration & Cutting.
2	87 KQX	888.1500	I	Goniometer, AC-Powered.
2	87 LBB	888.1240	II	Dynamometer, AC-Powered.
2	87 LOF	.....	III	Stimulator, Bone Growth, Noninvasive.
2	87 LWB	.....	III	Stimulator, Functional Neuromuscular, Scoliosis.
2	89 EGJ	890.5525	III	Device, Iontophoresis, Other Uses.
2	89 KTB	890.5525	II	Device, Iontophoresis, Specific Uses.
2	89 IKN	890.1375	II	Electromyograph, Diagnostic.
2	89 IKP	890.1225	II	Chronaximeter.
2	89 IKT	890.1385	II	Electrode, Needle, Diagnostic Electromyograph.
2	89 IMG	890.5860	II/III	Stimulator, Ultrasound and Muscle, for Use in Applying Therapeutic Deep Heat.
2	89 IPF	890.5850	II	Stimulator, Muscle, Powered.
2	89 ISB	890.1850	II	Stimulator, Muscle, Diagnostic.
2	89 LPQ	890.5860	II/III	Stimulator, Ultrasound and Muscle.
2	89 MBN	.....	III	Stimulator, Muscle, Powered, Invasive.
2	89 MKD	.....	III	Stimulator, Functional Walking Neuromuscular, Noninvasive.
2	90 LNH	892.1000	II	System, Imaging, Nuclear Magnetic Resonance.

Dated: June 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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